



# Medicare and Clinical Trials





Medicare offers people with Medicare the option to join some clinical trials for the diagnosis and treatment of illnesses. If you join a covered clinical trial, Medicare will pay some of the patient care costs.

## **What are clinical trials?**

Clinical trials are one of the final stages of a long and careful research process to help patients live longer, healthier lives. They test new types of medical care, like how well a new cancer drug works. The trials help doctors and researchers see if the new care works and if it is safe. They may also be used to compare different treatments for the same condition to see which treatment is better, or to test new uses for existing treatments.

All trials are based on a set of rules called a “protocol.” The protocol tells you

- who can or can't join the trial,
- how long the trial lasts,
- how often you will get tests or medications, and
- other details of the study.



## **Why do people join a clinical trial?**

People may choose to join a clinical trial to

- compare different treatments for the same condition to see which treatment is better.
- test new uses for existing treatments.
- gain access to new treatments that are not widely available.
- obtain medical care from doctors who lead in their field of medicine.
- help future patients with the same illness.

## **Why do people choose NOT to join a clinical trial?**

People may choose not to join a clinical trial because

- they are concerned about possible risks.
- some patients don't benefit from the new treatment.
- the trial may require more visits to the doctor, or the treatment takes more time than standard care.

Before you agree to take part in a trial, it will be explained to you. Then you will be asked to sign an informed consent form. This form describes the clinical trial and what is being tested. It will also explain any possible risks to you. Before you sign the form, ask questions so you understand and are comfortable with what will happen during the trial.



## Medicare Payment

**What costs does Medicare pay if I'm in a clinical trial?**

Medicare pays for routine costs. These include costs for items and services

- like room and board for a hospital stay that Medicare would pay even if you weren't in a trial.
- like an operation to implant an item that is being tested.
- to treat side effects and complications of the new care.

**Are there any costs that Medicare won't pay?**

Yes. Medicare will not pay for

- the new item or service that the trial is testing (except for certain devices).
- items or services provided only to collect data, and not used in your direct health care (such as monthly CT scans for a condition that usually requires one scan).
- items and services the trial gives you or any participant for no charge.
- coinsurance and deductibles.



## Other Insurance

**I'm in a Medicare Health Plan. Can I still be in a clinical trial?**

Yes. If you are in a Medicare Advantage Plan (such as an HMO, PPO, or Private Fee-for-Service Plan) or other Medicare Health Plan, you are entitled to the same coverage for clinical trials as a person in the Original Medicare Plan.

You can get your Medicare health care in different ways. You can stay in the Original Medicare Plan or choose to join a Medicare Advantage Plan or other Medicare Health Plan. The Original Medicare Plan is a fee-for-service plan that covers many health care services and certain drugs. You pay a set amount for your health care (deductible) before Medicare pays its part. Then, Medicare pays its share, and you pay your share (coinsurance or copayment) for covered services and supplies.

Medicare Advantage Plans and other Medicare Health Plans are plans that may cover more services than are covered by the Original Medicare Plan, and often have lower out-of-pocket costs. Medicare Health Plans will have one premium that includes coverage for Part A and Part B benefits, prescription drug coverage (if offered), and any extra benefits (if offered).



Once you join a clinical trial Medicare will pay for your covered services as if you were in the Original Medicare Plan. This means that your Medicare Health Plan can't keep you from joining a clinical trial. However, you should tell your plan before you start a clinical trial. That way, the plan can still keep track of your health care services.

Contact your Medicare Health Plan to find out what your coinsurance and deductible obligations would be if you joined a covered clinical trial.

### **Will my employer group health plan cover the routine costs in a clinical trial?**

Whether your employer plan covers all or some of the costs of these services depends on the following:

- The terms of the employer plan.
- Whether the employer plan or Medicare pays your bills first.

Before you join a trial, check with your employer group plan or the benefits administrator of the employer to find out what benefits are covered. Call 1-800-MEDICARE (1-800-633-4227) for a Medicare booklet on who pays first.



## **Will my Medigap (Medicare Supplement Insurance) policy pay for my coinsurance and deductibles if I am in a clinical trial?**

If the routine costs of your trial are covered by Medicare, then your Medigap policy must pay coinsurance amounts for those costs.

If your Medigap policy also covers deductibles and excess charges, it must also pay these amounts for routine services.

## **More Information**

**I want to find out more about clinical trials that might help me. What can I do?**

- Talk to your doctor.
- Look at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) on the web. This site lists government and private studies across the country. It also has more information to help you understand clinical trials. This site is a service of the National Library of Medicine. If you don't have a personal computer, your local library or senior center may be able to help you find this information.



## To find out about cancer trials

- Call 1-800-4-CANCER (1-800-422-6237) for more information. TTY users should call 1-800-332-8615. This toll-free Cancer Information Service provides cancer information and help locating cancer clinical trials. This is a service of the National Cancer Institute.
- Look at <http://cancertrials.nci.nih.gov> on the web. This site lists trials for patients with cancer, and detailed information about cancer clinical trials. This site is a service of the National Cancer Institute. If you don't have a personal computer, your local library or senior center may be able to help you find this information.